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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,312	02/12/2004	Wolfgang Geiger	32860-000688/US	4081

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EXAMINER	
TOOR, SADAF A	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/776,312	GEIGER, WOLFGANG	
	Examiner	Art Unit	
	Sadaf Toor	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 February 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/12/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to because reference numerals 3 and 4 appear to be mislabeled in Figure 2. Reference numerals 3 and 4 correctly illustrate the microneedle array and an individual microneedle in all other figures, but appear to be interchanged in Figure 2. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the

printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The abstract of the disclosure is objected to because legal phraseology is used ("said" in line 9). Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-3, 6-7, 14-8, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaylor et al. ('219) in view of Kreiser et al. ('843).

6. With Respect to claims 1 and 16, Kaylor et al. teach a healthcare network (best illustrated in Fig. 2) including a biosensor (20) which can include microneedle devices (see paragraph [0262]), a holding device for supporting the microneedle array (an article of clothing as described in paragraphs [0036], [0277], and [0310]), a data recording device connected to the microneedle array for recording data obtained from the microneedle array (biosensor (20) itself records the data and arrives at analyte measurement (60)), a data evaluation device connected to the data recording device for evaluating the recorded data (data allocation and processing (26)), and a display device connected to the data evaluation device for displaying data (measurement display and interpretation (62)). Kaylor et al. further disclose that the holding device can be an

article of clothing such as gloves (see paragraphs [0036], [0277], and [0310]). However, Kaylor et al. fail to teach that the display device is arranged on the holding device.

7. Kreiser et al. teach a hand-mounted device for obtaining a sample of blood from the scalp of a fetus and for measuring the pH of the blood sample. Fig. 1 shows the device (100) mounted on a surgical glove (102) as described in paragraph [0016]. A data evaluation device (pH electrode (128)) analyzes the blood and the result is displayed on the display means (electronic pH meter (132)). The display means (electronic pH meter (132)) is apparently part of the device (100); therefore, it is fully capable of being mounted on surgical glove (102) as well. It would have been obvious to one of ordinary skill in the art at the time the applicant's invention was made to combine the teachings of the Kaylor et al. biosensor system with the teachings of the hand-mounted pH measuring device of Kreiser et al., for the purpose of obtaining a diagnostic article with a display device arranged on the holding device or glove such that all components are disposed conveniently on the user's hand.

8. Referring to claims 2 and 17, Kaylor et al. further teach that a dosing unit (a drug delivery device as described in paragraphs [0258] and [0262]) can be fully attached or integrated with the biosensor. In particular, Kaylor et al. state that one or more microneedles first measure a biological condition in the blood or tissues of the body, then based on what is detected by a probe or other sensor (a data evaluation device) associated with one or more of the microneedles, other microneedles may deliver a therapeutic treatment. Since the dosing unit is attached or integrated with the biosensor, and the data evaluation device is associated with the microneedles of the biosensor, then the dosing unit itself is connected to the data evaluation device.

9. Referring now to claims 3, 7, and 18, the pH meter (128) of the Kreiser et al. device serves as both the data evaluating means and the data display means. As noted above, pH meter (128) is supported by the holding device (surgical glove (102)); therefore, it is integrated into the holding device.

10. With regard to claims 6, 14-15, and 21, the Kaylor et al. healthcare network relates to particular combinations of sensor technologies (biosensors which can include microneedle devices) and information management systems and/or health management systems for the benefit of the user, including embodiments wherein a degree of personal control over data sharing is maintained for user privacy. In essence, the purpose of this network is to provide a link between the data evaluating means of the diagnostic article and an electronic patient record, which would be contained in a management system.

11. Claims 4-5, 8-13, and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaylor et al. ('219) in view of Kreiser et al ('843) as applied to claims 1-3, 6-7, 14-18, and 21 above, and further in view of Olson ('113).

12. With regard to claims 4, 8-10, and 19, which claim the maximum height of a microneedle to be 2mm, Olson teaches microneedles and methods of manufacture and use thereof. In paragraph [0048] Olson states that microneedles used for minimally invasive penetration through a biological barrier usually have a height ranging from 200 to 2000 μm, which is equivalent to 0.2 to 2 mm.

13. With regard to claims 5, 11-13, and 20, which claim the maximum diameter of a microneedle lumen to be 150 μm, Olson further states (in paragraph [0048]) that microneedles

used for minimally invasive penetration through a biological barrier typically have a lumen diameter ranging from 70 to 150 μm. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to form the microneedles of Kaylor et al., as modified by Kreiser as discussed above, having the dimensions suggested by Olson as an obvious engineering design choice.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Anapliotis ('676) teaches a device for measuring the properties of endogenous fluids during a medical examination. Martin et al.('245) teach a device with an array of microneedles with a manipulating device. Stivoric et al. ('957) teach an apparatus for detecting, receiving, deriving and displaying human physiological and contextual information. Moerman et al. ('159) teach a combined lancet and electrochemical analyte-testing apparatus. Park et al. ('543) teach microneedle devices and production for transport of molecules across or into biological barriers, such as skin.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sadaf Toor whose telephone number is (703) 305-0474. The examiner can normally be reached on Monday - Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sat
8/9/04

:HLES MARMOR
:MARY EXAMINER